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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,239	03/31/1999	STEVEN A. GOLDMAN	19603/1426	8339

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/282,239	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of the specification in the paper of 5/27/2005, is acknowledged. Claims 25, 26 and 29 remain at issue and are present for examination.

Applicants' arguments filed on 5/27/200504, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 26 and 29 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al. (U.S. Patent No. 6,361,996 B1).

The rejection is stated in the previous office action as it applied to claims 25, 26 and 29. In response to this rejection applicants continue to traverse the rejection as it applies to the claims 25, 26 and 29.

For applicants convenience the previous rejection is repeated herein. Rao et al. teach an isolated, pure and homogeneous population of lineage-restricted

oligodendrocyte-astrocyte precursor cells which are capable of self-renewal and differentiation into oligodendrocytes and astrocytes and methods of generating, isolating and culturing such oligodendrocyte-astrocyte precursor cells. The specific pure homogeneous population of cells isolated by Rao et al. is illustrated in Figure 1 (See specifically cell type –14, and the supporting text) and while applicants specifically teach as an example said pure homogeneous preparation of cells as isolated from rat, applicants point out that the invention encompasses all mammalian neuroepithelial stem cells and is not limited to neuroepithelial stem cells from the rat. Mammalian neuroepithelial stem cells can be isolated from human and non-human primates, equines, canines, felines, bovines, porcines, ovines, lagomorphs, and the like. Thus, Rao et al. anticipates a claim to an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, wherein an oligodendrocyte specific promoter functions in all cells of the enriched or purified preparation.

Claims 25 and 26 which are drawn to the preparation of oligodendrocyte progenitor cells of claim 29 are included in this rejection because these product-by-process like limitations do not change the oligodendrocyte progenitor cells of claim 29. Rao further teach that a better understanding of a number of tumors and other diseases in humans could be facilitated by a better understanding of these cell types and the ability to isolate and grow these mammalian cells in vitro, which allows for the possibility of using such stem cells to treat neurological disorders in mammals, particularly humans. Further, such mammalian neuroepithelial stem cells can be used therapeutically for treatment of certain diseases, e.g. Parkinson's Disease, such as by

transplantation of such cells into an afflicted individual. Moreover, such cells can still further be used for the discovery of genes and drugs that are useful for treating certain of these diseases.

One of ordinary skill in the art at the time of filing would have been motivated to use the methods taught by Rao et al. to isolate an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells from humans so that these pure cell preparations could be used to treat neurological disorders in humans, such as. Parkinson's Disease, such as by transplantation of such cells into an afflicted individual. This motivation is suggested by Rao et al. and the reasonable expectation of success comes from the results of Rao et al. who successfully isolated such an enriched or purified preparation of mitotic oligodendrocyte progenitor cells from rat.

Applicants continue to traverse this rejection and additionally present a second Declaration of Mahhendra S. Rao, M.D. Ph.D. under 37 C.F.R. 1.132 ("Second Rao Declaration"). Applicants assert that this declaration is presented to demonstrate why the subject matter of the '996 Patent is very different from that of the present patent application. In acknowledging applicant's arguments and the above mentioned declaration, applicants are reminded that the current claims, 25, 26 and 29, stand rejected as anticipated by Rao et al.('996 Patent). This rejection is made in spite of the acknowledged differences between the preparations taught by Rao et al. and those disclosed by the instant application.

Applicants continue to argue the previous rejection on the basis of the differences between the preparations taught by the Rao et al. patent and the preparations taught by the instant application. Applicants submit that the '996 Patent teaches that the astrocyte/oligodendrocyte precursor cells (14 and 54) differentiate directly into two cell types (i.e. astrocytes and oligodendrocytes). Applicants further submit that from clonal analysis there is a homogenous population of astrocytes/oligodendrocyte precursor cells which generate oligodendrocytes and two kinds of astrocytes by the process described in the Rao et al. patent. Applicants further submit that there are multiple pathways to generate post-mitotic, mature oligodendrocytes, and submit a number of references illustrating such and finally conclude that each of these cell types are very different from the oligodendrocyte-specified progenitor cells of the present application.

Applicants complete argument is acknowledged, and while it is agreed that the various different cell types taught by the references discussed by applicants are different from "the oligodendrocyte-specified progenitor cells of the present application", it remains that the cell preparation taught by Rao et al. anticipates or makes obvious the "claimed enriched or purified preparation of mitotic oligodendrocyte-specified progenitor cells". Applicants are again reminded that it is the **claimed** enriched or purified preparation of human mitotic oligodendrocyte-specified progenitor cells that is anticipated by Rao et al., not a particular enriched or purified preparation of human mitotic oligodendrocyte-specified progenitor cells **taught by applicant's specification**.

Applicants further traverse the rejection on the basis that applicants have presented evidence in the 2nd Rao declaration demonstrating the patentability of the claims. Specifically applicants state that the 2nd Rao declaration clearly demonstrates that the PTO's case that the claimed oligodendrocyte-specified progenitor cell is inherently present in the '996 patent is wrong. Applicant's statement that the 2nd Rao declaration clearly evidences such, with respect to the claims is questioned. The 2nd Rao declaration makes many statements with respect to the cell population taught by the Rao et al. patent and the instant specification, however, makes no comment much less evidences anything with respect to the cell population **claimed**. Applicants continually attest, as does the second Rao declaration, that there are differences between the cell populations taught by Rao et al. and those taught by the instant application. While acknowledged, such differences are irrelevant in light of the cell population **claimed**. It is the cell population claimed that is anticipated or made obvious by the Rao et al. patent, not the cell populations taught by the specification.

Applicants further traverse claim 26 on the basis that the adult progenitor cells of claim 26 possess an unobvious difference from the fetal-derived cells of the 996 Patent and that this has been completely overlooked in the outstanding office action. Applicants point is acknowledged as it has been previously, however, it remains that the cell preparations taught by Rao et al. continue to anticipate or make obvious the claimed cell preparations for the reasons previously made of record.

As discussed previously and above, applicants submission of the differences between the cells taught by Rao and the cells taught in the instant application as

isolated from human are acknowledged and understood, however, applicant is reminded that applicants invention as disclosed by applicants specification and applicants invention as encompassed by the rejected claims are not necessarily the same invention and that applicants should direct their arguments to the rejected claims, not applicants specification. As discussed above and previously, applicants claimed invention is anticipated by or, in the alternative, obvious over Rao et al. Applicants continue to argue that based on the above using the teachings of Rao et al. one of skill in the art would not have a reasonable expectation of success in achieving the oligodendrocyte-specified progenitor cell preparation as taught by the instant specification because the cells of Rao are in a less differentiated state then that of the instant invention. While this may be true, it remains to be seen that the cell preparation taught by Rao continues to anticipate an enriched or purified preparation of human mitotic oligodendrocyte-specified progenitor cells including those wherein the cells are derived from a post-natal or an adult human, (see previous comments to product-by process issues), wherein cyclic nucleotide phosphodiesterase 2 promoter is transcriptionally active in all cells of the enriched or purified preparation. As discussed above, the preparation taught by Rao is such that a cyclic nucleotide phosphodiesterase 2 promoter is transcriptionally active in all cells of the enriched or purified preparation inherently and applicants in their responses have not addressed this point.

Applicants continue to argue the differences between the cell population taught by Rao et al. and that taught by the instant specification. This complete argument is

again acknowledged, as the above and previous arguments, but found non-persuasive for the same reasons discussed above, that the difference between that cell population taught by Rao et al. and that cell population taught by the instant specification are not necessarily relevant to that cell population claimed. It is that cell population claimed that remains rejected for the reasons stated above and previously.

As discussed previously and above, Rao et al. teach an isolated, pure and homogeneous population of lineage-restricted oligodendrocyte-astrocyte precursor cells which are capable of self-renewal and differentiation into oligodendrocytes and astrocytes and based on the above evidence, the cyclic nucleotide phosphodiesterase 2 promoter is inherently transcriptionally active in all cells of the enriched or purified preparation. While applicants specifically teach as an example said pure homogeneous preparation of cells as isolated from rat, applicants point out that the invention encompasses all mammalian neuroepithelial stem cells including those isolated from human and non-human cells.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

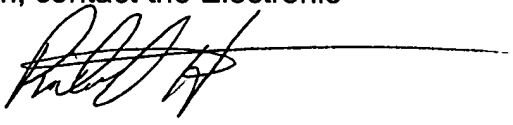
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
8/3/2005